# 510(K) SUMMARY (as required by 807.92(c))

Submitter of 510(k):

**Dynarex Corporation** 

10 Glenshaw Street Orangeburg, NY 10972

USA

Phone: (845) 365-8200 Fax: (845) 365-8201

Contact Person:

Daniel Consaga

Date of Summary:

December 20, 2010

Trade/Proprietary Name:

Dynarex Ultrasound Gel.

Classification Name:

Diagnostic Ultrasonic Transducer

**Product Code:** 

MUI

Intended Use:

Dynarex Ultrasound Gel is intended for use as the coupling medium for ultrasound procedures on external, intact skin. Not for use with defibrillators.

#### **Device Description:**

Dynarex Ultrasound Gel is a viscous, clear blue, water soluble gel. Typical packaging configurations for the Dynarex Ultrasound Gel is 250 ml plastic bottle, 1 Liter plastic bottle and 5-liter plastic container. Other sizes may become available.

#### **Predicate Device:**

LiquaSonic Ultrasound Gel 510k Number K841871 manufactured by CHESTER LABS, INC. Erlanger, KY 41018.

#### Substantial Equivalence:

The Dynarex Ultrasound Gel provides an effective coupling between the tissue being examined and the ultrasound unit. Its function and performance are similar to the predicate device as presented in this 510(k)

#### Safety and Effectiveness of the device:

This device is as safe and effective as the predicate device cited above. This is better expressed in the Test Report for ISO 10993 and Test Report Number HIA\_DYN\_GEL\_AM Dated August 27, 2008.

# 510(K) SUMMARY (as required by 807.92(c))

Summary comparing technological characteristics with other predicate device:

Dynarex Ultrasound Gel is similar in terms of intended use and technological characteristics to predicate devices reviewed as coupling gels used to couple ultrasound devices to skin. The device is substantially equivalent with respect to indications for use and other physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

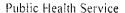
Please find below a tabulated comparison supporting that this device is substantially equivalent to the predicate device in commercial distribution.

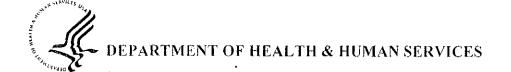
TECHNOLOGICAL CHARACTERISTICS	Dynarex Gel Comparison to LiquaSonic Ultrasound Gel – 510K # K841871	
Indications for use	Substantially Equivalent	
Target Population	Substantially Equivalent	
Materials	Substantially Equivalent	
Biocompatibility	Substantially Equivalent	
Anatomical sites	Substantially Equivalent	

### **Performance Summary:**

FDA has not established special controls or performance standards for this device.

TECHNOLOGICAL CHARACTERISTICS Performance	Dynarex Ultrasound Gel 510K # K102637	LiquaSonic Ultrasound Gel 510K # K841871
Acoustic Speed Measurement (m/s)	1530.1	1549.5
Acoustic Attenuation Coefficient – Avg. 3 Lots (dB/cm/MHz)	0.04 +/- 0.018	< 0.05
Acoustic Impedance Measurement (MRayl)	1.505	1.561
Electroconductivity Avg. 3 Lots (mS/cm)	1.930 +/- 0.026	1.349 +/- 0.003





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room – WO66-G609 Silver Spring, MD 20993-0002

Mr. Daniel Consaga Quality Engineer Dynarex Corporation 10 Glenshaw Street ORANGEBURG NY 10962

FEB 16 204

Re: K102637

Trade/Device Name: Dynarex Ultrasound Gel

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic Ultrasound transducer

Regulatory Class: II Product Code: MUI

Dated: December 20, 2010 Received: January 10, 2011

### Dear Mr. Consaga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Parts 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>.

Sincerely Yours,

Mary Pastel, ScD.

Director

Division of Radiological Devices

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Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Dynarex Ultrasound Gel

510(k) Number (if known): K102637

Device Name:

Indications for Use:		•
Dynarex Ultrasound Gel is into the any Ultrasound System, U natal scans.	ended for use as litrasound proced	an ultrasound coupling media for use with dures including diagnostic and elective pre-
pulsed echo imaging system. beam into body tissue to dete	The gel is intend rmine the depth	ve gel media used with ultrasonic led to facilitate projecting a pulsed sound or location of the tissue interfaces and to in the transmitter to the tissue interface and
Apply the ultrasound gel to the towel. For external use only.	e treatment area.	. Remove after treatment with a tissue or
Contraindications: Not for use	with defibrillator	S.
Prescription UseX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW	THIS LINE-CONTI	NUE ON ANOTHER PAGE IF NEEDED)
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Canaussanaa	of CDDU Office	- Device Evaluation (SPE) 6 HI)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety